K052298

510(k) SUMMARY

DEC 12 2006

Percutaneous Systems, Inc.'s CYSTOGLIDE INTRODUCER SHEATH Advertising Claims

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Percutaneous Systems, Inc.
1300 Crittenden Lane, #101
Mountain View, CA 94043-1359

Phone: (650) 969-8800 x 204
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Contact Person: Thomas Lawson

Date Prepared: August 15, 2005

Common or Usual Name

Urology Introducer Sheath

Classification Name

Accessories, Catheter, G-U

Predicate Device

PSI's UPDATED SLIP Urology Introducer Sheath
Astra Tech's LoFric catheter
Rusch's MMG/O'Neil catheter

Intended Use / Indications for Use

The CYSTOGLIDE INTRODUCER SHEATH is intended to facilitate the introduction of catheters or instruments into the urethra. The CYSTOGLIDE INTRODUCER SHEATH is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

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Technological Characteristics

The CYSTOGLIDE INTRODUCER SHEATH consists of a film, a sheath, a stabilizing ring, and an obturator. The sheath is isolated from the skin microflora by the ViaShield film membrane.

Performance Data

Performance data demonstrated no significant difference in the performance of the CYSTOGLIDE INTRODUCER SHEATH and the predicate devices.

Substantial Equivalence

The CYSTOGLIDE INTRODUCER SHEATH has similar intended use, indications for use, principles of operation and technological characteristics as the predicate devices. The CYSTOGLIDE INTRODUCER SHEATH is substantially equivalent to the cleared UPDATED SLIP Urology Introducer Sheath, the LoFric Intermittent Catheter and the MMG/O'Neil catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 12 2006

Thomas Lawson, Ph.D.
VP, Clinical and Regulatory Affairs
Percutaneous Systems, Inc.
1300 Crittenden Lane
Suite 101
MOUNTAIN VIEW CA 94043

Re: K052298
Trade/Device Name: CYSTOGLIDE INTRODUCER SHEATH
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: October 11, 2006
Received: October 12, 2006

Dear Dr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: CYSTOGLIDE INTRODUCER SHEATH

Indications for Use:

The CYSTOGLIDE INTRODUCER SHEATH Urology is intended to facilitate the introduction of catheters and instruments into the urethra.

The CYSTOGLIDE INTRODUCER SHEATH is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

Prescription Use ___X_____ ~~AND~~/OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052298

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